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| 09/824,625      | 04/02/2001  | Albert S. Lee        | 22727-66            | 8907             |

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EXAMINER

SCHOPFER, KENNETH G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3739

DATE MAILED: 07/03/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/824,625

Applicant(s)

LEE ET AL.

Examiner

Kenneth G Schopfer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 15, 17-19 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) 20-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 17-19 and 46-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 7, 8, 12, 19, 46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenberg (USPN 4010795) in view of Falk (USPN 5456702).
3. Referring to claims 1-5, 7, 8, 19, and 49, Stenberg teaches all of the limitations of these claims except for the first and second temperature sensors. Stenberg teaches an apparatus for thermally affecting tissue including an implantable member 5 having an outer surface for contacting tissue and a fluid-tight lumen 8 configured to receive a cooling liquid. The implantable member has an oval coil shape and is formed from a flexible, heat conductive, and biocompatible material. Further, the implantable member can be placed in contact with epidural or subdural brain tissue. Finally, the implantable member is formed of shape memory material, formable metal wire 9 (column 2, lines 4-7). Falk teaches a similar device having two temperature sensors, the first 220 for measuring the temperature of target tissue and the second 210 for measuring the temperature of the fluid in a lumen of the device. It would have been obvious to one of ordinary skill in the art at the time of invention to include two temperature sensors as in Falk, one in the lumen to measure the fluid temperature and one to measure the tissue temperature, in the device of Stenberg in order to ensure safe and effective use of the device.

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4. Referring to claim 46, the combined device of Stenberg and Falk teaches all of the limitations of this claim as described above except for the first temperature sensor being positioned on a tissue-contacting portion of the implantable member. It would have been obvious to one of ordinary skill in the art at the time of invention to place the first temperature sensor on a tissue-contacting surface of the device in order to effectively measure the treated tissue directly adjacent the treatment device.

5. Claims 6, 9-11, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenberg (USPN 4010795) in view of Falk (USPN 5456702) as applied to claims 1 and 5 above, and further in view of Daily (USPN 5609620).

6. Referring to claim 6, Stenberg and Falk teach all of the limitations of this claim as described above except for the implantable member being formed from a silicone elastomer. Daily discloses an apparatus for thermally affecting tissue that may be formed from a silicone elastomer (column 3, line 18). It would have been obvious to one of ordinary skill in the art at the time of invention that the device of Stenberg and Falk could have been made from silicone as in the device of Daily as a suitable heat conductive and biocompatible material.

7. Referring to claims 9-11, Stenberg and Falk teach all of the limitations of these claims as described above except for the backing member. Daily teaches an apparatus for thermally affecting tissue that includes a backing member 56 made of silicone that is in thermal contact with tissue and is inherently designed to resist adherence to tissue. It would have been obvious to one of ordinary skill in the art at the time of invention to include a backing member as in Daily in the device of Stenberg and Falk to provide the device with a flat thermal transmission surface.

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8. Referring to claim 47, the combined device of Stenberg, Falk, and Daily teaches all of the limitations of this claim as described above except for the first temperature sensor being positioned on the backing member. It would have been obvious to one of ordinary skill in the art at the time of invention to place the first temperature sensor on the backing member of the device in order to effectively measure the treated tissue directly adjacent the treatment device.

9. Claims 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenberg (USPN 4010795) in view of Falk (USPN 5456702) as applied to claim 1, and further in view of Goble et al. (USPN 5891134).

10. Referring to claims 15, 17, and 18, Stenberg and Falk teach all of the limitations of these claims as described above except for the pressure measurement element. Goble et al. teach an apparatus for thermally affecting tissue including a pressure sensor 58 and pressure warning alarm 62 in order to ensure that the fluid pressure in the device does not adversely affect the device and surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time of invention to include a pressure measurement element as in Goble et al. between the implantable member and the tissue in the device of Stenberg and Falk to ensure that the pressure exerted by the device does not harm surrounding tissue.

11. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stenberg (USPN 4010795) in view of Geremia et al. (USPN 5108407).

12. Referring to claim 48, Stenberg teaches all of the limitations of these claims except for the shape memory material being deformed under a force and returning to an at-rest shape after removal of the force. Stenberg teaches an apparatus for thermally affecting tissue including an implantable member 5 having an outer surface for contacting tissue and a fluid-tight lumen 8

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configured to receive a cooling liquid. The implantable member has an oval coil shape and is formed from a flexible, heat conductive, and biocompatible material. Further, the implantable member can be placed in contact with epidural or subdural brain tissue. Finally, the implantable member is formed of shape memory material, formable metal wire 9 (column 2, lines 4-7).

Geremia et al. teach that it is well known in the art to use shape memory materials that change shape in response to external forces in implantable devices (columns 2-3). It would have been obvious to one of ordinary skill in the art at the time of invention to make the coil of Stenberg out of shape memory material as described in Geremia et al. to ensure that the implantable device better conforms to the area of tissue that will be treated by the device.

#### *Response to Arguments*

13. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### *Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth G Schopfer whose telephone number is 703-305-2649. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

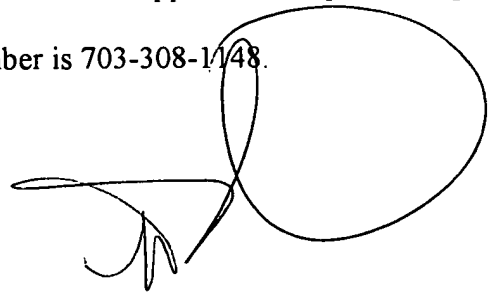
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

KS

KS

June 24, 2003

A handwritten signature in black ink, consisting of a large, stylized 'L' and 'D' followed by a horizontal line and a small flourish.

LINDA C. M. DVORAK  
SUPERVISORY PATENT EXAMINER  
GROUP 3700